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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,826	01/17/2001	Nancy Tommye Jordan	03073.0001U2	8834

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EXAMINER

CHIN, CHRISTOPHER L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/764,826

Applicant(s)

Jordan et al

Examiner

Chris Chin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 24, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4, 9, 10, and 15-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 26 is/are allowed.
- 6) ☒ Claim(s) 5, 6, and 11-14 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 23, and 24 is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 5, 6, 11, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Morton et al for the reasons of record.

In response to this rejection Applicants argue that the early pregnancy factor detected in the method of Morton et al is not the early conception factor detected in the claimed method. The early conception factor detected in the instant invention has a molecular weight between 190,000 and 205,000 daltons.

Applicant's arguments have been considered but are not convincing. The instant claims rejected over Morton et al do not recite an molecular weight limitations. Therefore, the early pregnancy factor detected in the method of Morton et al is considered to read on the early conception factor recited in the instant claims since there is no distinction between the two factors recited in the instant claims.

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Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morton et al in view of May et al.

See above for the teachings of Morton et al.

Morton et al differs from the instant invention in failing to teach alkaline phosphatase, horseradish peroxidase, or colloidal gold as a detectable moiety.

May et al (EP 0 291 194) teaches the use of alkaline phosphatase, horseradish peroxidase, or colloidal gold as detectable moieties conjugated to analyte specific antibodies in immunoassays (page 4, lines 42-55).

It would have been obvious to one of ordinary skill in the art to use alkaline phosphatase, horseradish peroxidase, or colloidal gold, as taught by May et al, in the method of Morton et al because Morton et al generically teaches the use of enzymes as a detectable moiety and May et al show that alkaline phosphatase and horseradish peroxidase are conventional detectable moieties used in immunoassays, such as the assay of Morton et al. It also would have been obvious to use colloidal gold, as taught by May et al, in the method of Morton et al because May et al show that

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colloidal gold is an obvious alternative to enzymes as a detectable moiety in immunoassays and colloidal gold provides the advantage of obviating the need for additional reagents, such as enzyme substrates, that are required when enzymes are used.

Allowable Subject Matter

5. Claims 7, 8, 23 and 24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 25 and 26 are allowed.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
December 6, 2003



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641